**MedImmune, Inc.**

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December 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room l-23
Rockville, MD 20857

**RE: Docket No. 99D-4396**

Dear Ladies and Gentlemen:

MedImmune has reviewed the proposed Guidance for the Industry Document, "Financial Disclosure by Clinical Investigators", published in the October 26, 1999 Federal Register and would like to submit the following comments to the FDA.

**Collection and Documentation of Financial Interest Information**

Referring to question and answer 28 of the draft guidance document, which notes "In addition to letter and mail receipts, the applicant should retain complete records showing any financial interest or arrangements as described in the financial disclosure final rule(s) entered into between the applicant or sponsor of the covered study and the clinical investigator. In addition to correspondence and copies . . . applicants should retain appropriate financial documentation regarding the payments the applicant has made to investigators (for example, check stubs, canceled checks, records of direct electronic financial transactions...)." It is MedImmune's opinion that the development of a system to track and maintain the above cited information would be a significant burden as the number of investigators used for various clinical studies worldwide could potentially number in the thousands. MedImmune would also like to comment on an FDA statement made at the November 1, 1999 DIA conference, "Financial Disclosure by Clinical Investigators, A Guide to Implementation". Ms. Mary Gross of the FDA noted that the panel convened at that meeting determined that collecting and maintaining questionnaires with information supplied from the investigators would be sufficient under the rule for 2 1 CFR 54. Ms. Gross also noted that investigators would have to be sufficiently trained and the sponsor would have to conduct due diligence in obtaining the original financial disclosure information questionnaire as well as the information at the one-year follow-up. MedImmune agrees with this decision and requests that this policy be detailed in the final guidance document.

**Travel Expenses**

Although not discussed in the guidance document, this topic was discussed at the November 1, 1999 meeting discussed above. During this meeting the FDA panel stated that travel and entertainment expenses are to be included as Significant Payments of Other Sorts (SPOOS). It is MedImmune's opinion that reimbursement of travel expenses should not be included in

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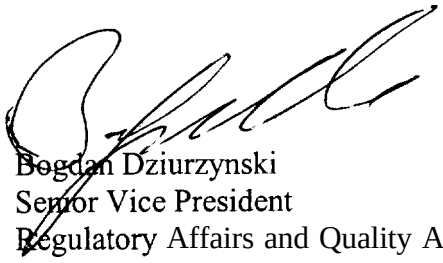
SPOOS. Whereas grants and honoraria provide direct financial benefit to an Investigator, travel expenses are merely reimbursement of expenses encountered by an investigator while conducting business for a sponsor. As it is current business and government policy to not include business travel as part of gross salary, it is MedImmune's belief that travel expenses are not to be included in SPOOS. Therefore, MedImmune respectfully requests that the Agency reconsider its position on this point.

Thank you for the opportunity to review and comment on this proposed guidance.

Sincerely,



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